MEDICAL AND SCIENTIFIC PERSPECTIVE ON SAFETY OF BREATHABLEBABY® MESH CRIB LINERS

MICHAEL S. SCHECHTER, MD, MPH*

PETER C. RAYNOR, PHD†

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SUSAN KLOBUCHAR, BREATHABLEBABY®, LLC

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* Dr. Schechter is Professor and Chief of the Division of Pulmonary Medicine in the Department of Pediatrics at Children's Hospital of Richmond (CHOR) at Virginia Commonwealth University (VCU) and Director of the VCU cystic fibrosis center and CHOR community asthma program. He has previously been on the faculty of Harvard, Wake Forest, Brown, and Emory Universities. He has served on numerous committees of the Cystic Fibrosis Foundation, American Thoracic Society, and American Academy of Pediatrics (AAP), and is immediate past chair of the AAP Section of Pediatric Pulmonology and Sleep.

Dr. Schechter is an epidemiologist whose research has been primarily concerned with environmental and sociodemographic influences on outcomes in CF, and he has also worked with the CF Foundation, CDC, Spina Bifida Association, and other groups on fostering methods to improve the quality of care and outcomes for children with chronic illness.

Dr. Schechter has been an invited speaker at a host of national and international conferences, and has an extensive record of published research, reviews, commentaries, edited books and book chapters.

† Dr. Raynor is an Associate Professor in the Division of Environmental Health Sciences at the University of Minnesota School of Public Health, holds a B.S. in Chemical Engineering, with distinction, from Cornell University and M.S. and Ph.D. degrees in Environmental Sciences & Engineering from the University of North Carolina at Chapel Hill. His research and teaching interests revolve around the assessment and control of environmental exposures, especially those occurring in workplace environments. He has special expertise in air filtration and flow through porous media. Dr. Raynor directs the University of Minnesota Industrial Hygiene Program and the Midwest Emerging Technologies Public Health and Safety Training Program.

ABSTRACT

Recent reports have brought the potential risks of crib bumper pads to public attention. It has been suggested that mesh crib liners may mitigate these risks. This medical perspective reports on a review of existing epidemiologic studies as well as 2 technical studies that were commissioned to summarize and evaluate the available scientific evidence regarding BreathableBaby's mesh crib liner products. The authors present a review of literature on control of breathing and respiratory mechanics in infants and the mechanism of bedding-related asphyxiation; summarize an independent epidemiologic analysis of Consumer Product Safety Commission (CPSC) hazard monitoring data on morbidity and mortality associated with crib bedding; and summarize laboratory testing data from 2 independent laboratories regarding air permeability of the BreathableBaby Mesh Liners.

The epidemiologic analysis found that, with respect to mesh crib liners, there were no reports of fatalities, injuries treated in emergency departments, injuries that required medical attention, or incidents that involved a risk of suffocation. These findings are in line with a report published in an academic medical journal in 2016. Testing done in the laboratory of Dr. Raynor (one of the authors of this report) found that the pressure required to maintain physiologic airflow across the mesh liners was more than two orders of magnitude lower than the maximum inspiratory and expiratory pressures that infants can generate. The relatively minimal pressure drop associated with the BreathableBaby liners suggests that they are likely to have minimal impact on the inspiration and exhalation rates of infants were they to breathe directly through the crib liners. Testing by a second independent laboratory found the least permeable BreathableBaby crib liner allows 8X or greater air flow relative to any of the traditional crib bumpers in these tests.

In summary, we believe that the combination of laboratory and epidemiologic data make a compelling argument for the safety of the BreathableBaby products. These mesh crib liners do not appear to present a significant restriction to infant breathing airflows, and there is no reason to believe that they would increase the risk of suffocation hazards for infants. Ongoing surveillance through the established CPSC databases would, nonetheless, be appropriate to confirm this conclusion.

REPORT

BACKGROUND & OBJECTIVES

BreathableBaby®, LLC is a small company based in Minnesota that manufactures mesh crib liners as an alternative to traditional crib bumpers. BreathableBaby asserts that its mesh crib liner is safer than a traditional crib bumper, providing the utility of preventing limb entrapment but with no potential threat of suffocation, and that its mesh crib liners are breathable because they are mostly made up of permeable materials.

A paper by Thach et al published in 2007 brought the potential risk of crib bumper pads to public attention, by reporting on 27 accidental deaths they found in the Consumer Product Safety Commission (CPSC) databases that were attributed to crib bumper pads by medical examiners[1]. Following this, the American Academy of Pediatrics, the Canadian Pediatrics Society, and the National Institutes of Health recommended against their use and 2 jurisdictions banned their sale[2-4]. However, a recent update of the CPSC database analysis published in 2016 by NJ Scheers et al found an apparent increase in the incidence of suffocation deaths attributable to crib bumpers since their previous report[4]. Notably, they found no evidence that other objects or clutter in the cribs could be blamed for these deaths, refuting an argument made following their initial publication.

In their discussion, Scheers et al distinguished traditional crib bumpers from mesh products such as those manufactured by BreathableBaby, stating that *"[N]ontraditional bumper designs seem to mitigate some of the problems found with traditional crib bumpers. Mesh bumpers (sic) are breathable and thin and may reduce the likelihood of slat entrapment and climb outs."*

The current report was commissioned by BreathableBaby to summarize the available scientific evidence regarding their mesh crib liner products. The authors of the report are Michael S. Schechter, MD, MPH, a pediatric pulmonologist and Professor of Pediatrics at Virginia Commonwealth University Health Sciences Center, and Peter C. Raynor, an environmental engineer and Associate Professor of Environmental Health Sciences at the University of Minnesota School of Public Health. The report will provide a review of literature regarding neonatal and infant control of breathing and respiratory mechanics of relevance to potential suffocation risk; describe new data on the epidemiology of any adverse events associated with

BreathableBaby products; provide the results of laboratory testing data on air permeability of the BreathableBaby Mesh Liners; and discuss the implications of all of these findings in regard to infant safety.

METHODS

1. Review of Literature on control of breathing and respiratory mechanics in infants and mechanism of bedding-related asphyxiation

Introductory text on mechanisms and control of breathing were summarized from standard textbooks. A literature review was performed by Dr. Schechter in April 2016 through a search of PubMed using search terms including “lung compliance”, “respiratory muscles/physiology”, “airway obstruction”, “asphyxia” “sudden infant death” and “nasal obstruction”, all limited to infancy. The bibliography and references of articles discovered through this search were reviewed to look for additional papers of interest.

2. Epidemiologic data on morbidity and mortality associated with BreathableBaby Mesh Liners

BreathableBaby commissioned Econometrica to conduct an independent epidemiologic analysis of Consumer Product Safety Commission (CPSC) hazard monitoring data to determine the frequency and nature of any incidents associated with mesh crib liners and the frequency and type of injuries associated with limb entrapment in cribs. These issues were analyzed using incident data available from four major CPSC hazard monitoring databases:

- The National Electronic Injury Surveillance System (NEISS) contains reports of product-related injuries involving children from a statistically structured sample of approximately 100 hospital emergency departments (EDs).
- The Injury and Potential Injury Incidents (IPII) database is a compilation of product-related incidents – fatalities, injuries, and no-injury cases – reported to the CPSC from a number of sources, including reports from consumers.
- The In-Depth Investigation (INDP) summary database provides date, demographic, and injury information for injuries, fatalities and other incidents for which CPSC staff or contractors conducted a telephone or on-site investigation.
- The Death Certificates (DTHS) file provides date, demographic, and limited incident information for some but not all fatal injuries associated with consumer products.

Their review included all incidents associated with cribs and crib bedding involving children age 3 to 15 months and was completed in April 2016. It should be noted that these are the same databases accessed and reported on by Scheers et al for their paper[4].

3. Laboratory testing data on air permeability of the BreathableBaby Mesh Liners

A. Dr. Raynor conducted tests to measure the ease with which crib liners made by BreathableBaby permit air flow through their fabrics. Four crib liner fabrics created by BreathableBaby were evaluated in these studies. They are designated as follows:

(a) BreathableBaby Mesh Crib Liner
(b) BreathableBaby Deluxe Cableweave Crib Liner
(c) BreathableBaby Ultra Luxe Mesh Crib Liner
(d) BreathableBaby Deluxe Embossed Crib Liner

Tests were conducted on two occasions, in February and June of 2015. The Mesh Crib Liner and the Deluxe Cableweave Crib Liner were tested in February. The Mesh Liner was tested along with the Ultra Luxe Mesh Crib Liner and the Deluxe Embossed Crib Liner in June.

An image of the test apparatus is shown in Figure 1. On each occasion, measurements were made three separate times with each of the test fabrics and three times with no test fabric present. When used, test fabrics were placed with the surface that would face an infant upward on top of a porous frame that allowed the rear of the fabric to be exposed to room air.

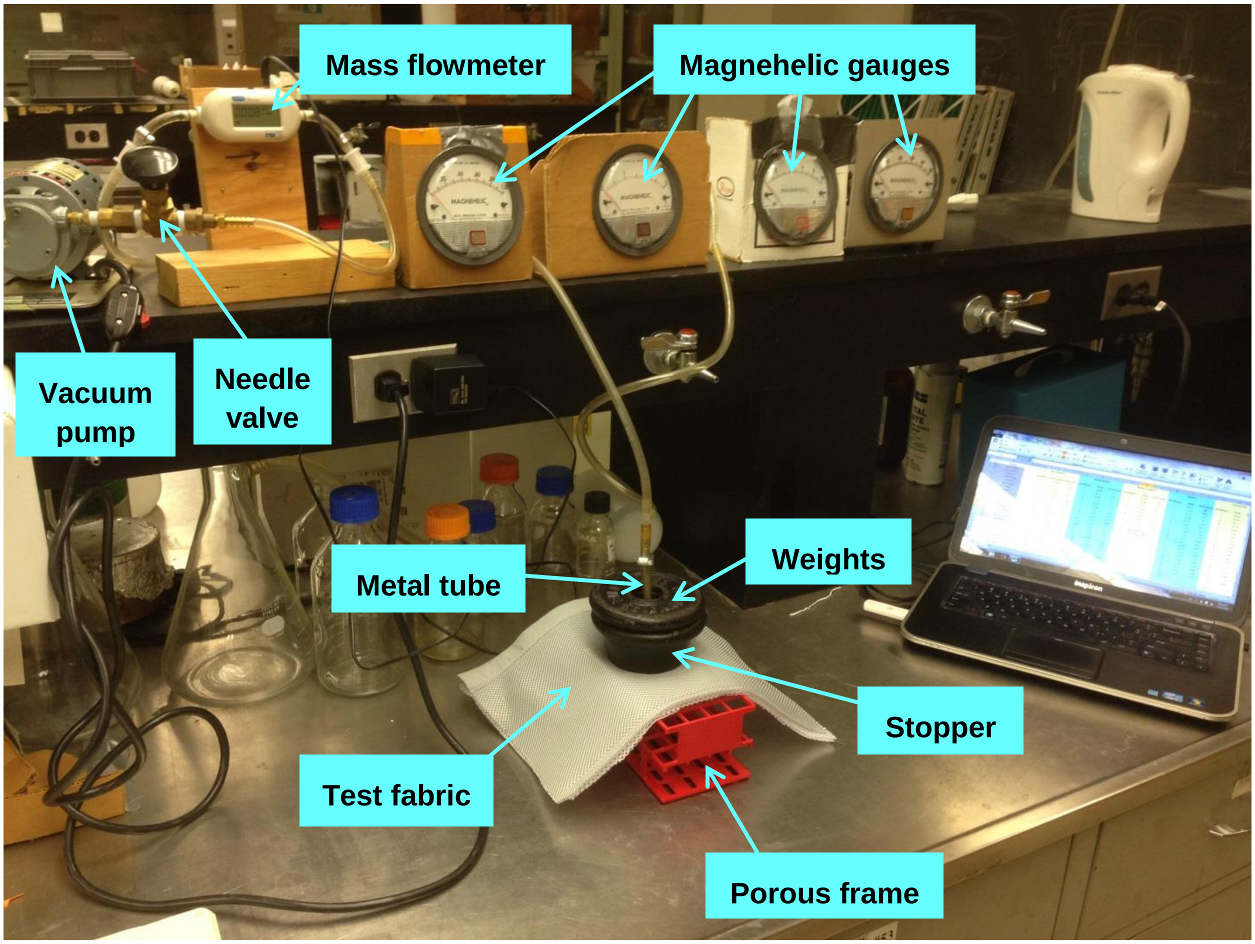


FIGURE 1. An image of the test apparatus.

A small metal tube 3/16 inch (4.8 mm) in diameter, approximately the diameter of an infant's nostril, was inserted through a hole in a large rubber stopper. The end of the tube was even with the bottom of the stopper. When fabrics were being tested, the tube and stopper were placed flat on top of the liner fabric. When measurements were made without a test fabric, the tube and stopper were placed flat on top of the porous frame so that the tube was open to the room air. To approximate the weight of an infant's head, 5 pounds (2.3 kg) of weights were applied in all cases on top of the stopper.

Air was drawn through the metal tube and connected plastic tubing using a vacuum pump. The air flow rate was controlled using a needle valve just upstream from the vacuum pump. Flow through the system was measured in liters per minute (L/min) by a mass flowmeter (TSI Inc., Shoreview, MN). Resistance to air flow was determined by comparing the pressure taken at a point just downstream from the stopper to the room pressure. This pressure drop was monitored by four Magnehelic pressure gauges with ranges of 0-1, 0-3, 0-10, and 0-50 in. H_2O. The pressure drop readings were converted to units of cm H_2O for later analysis[‡].

During each run, 10 measurements of air flow rate and pressure drop were made. Flow rates were adjusted prior to each measurement using the needle valve to obtain readings that spanned the range of measurable flow rates and pressure drops. Measurements were limited by the maximum flow rate, approximately 25 L/min. Therefore, a total of 30 paired measurements of flow rate and pressure drop were made for each fabric – and when no fabric was present – spanning the practical range of measurements possible with the apparatus.

For each liner, and for the runs when no fabric was present, the readings of pressure drop were plotted against the corresponding readings of air flow rate. Using only measurements with air flow less than 12 L/min, a second-order polynomial regression equation was fit through the data for each fabric with an intercept of zero. For each liner, the fitted second-order regression equation when no fabric was present was subtracted from the regression equation for the fabric to produce a new second-order polynomial equation that estimated the performance of the fabric by itself without any effects from the test apparatus. Using these equations – one for each fabric – estimates were made of the pressure drop at flow rates of 4 and 8 L/min, which were chosen to approximate average and instantaneous maximum inhalation rates for infants.

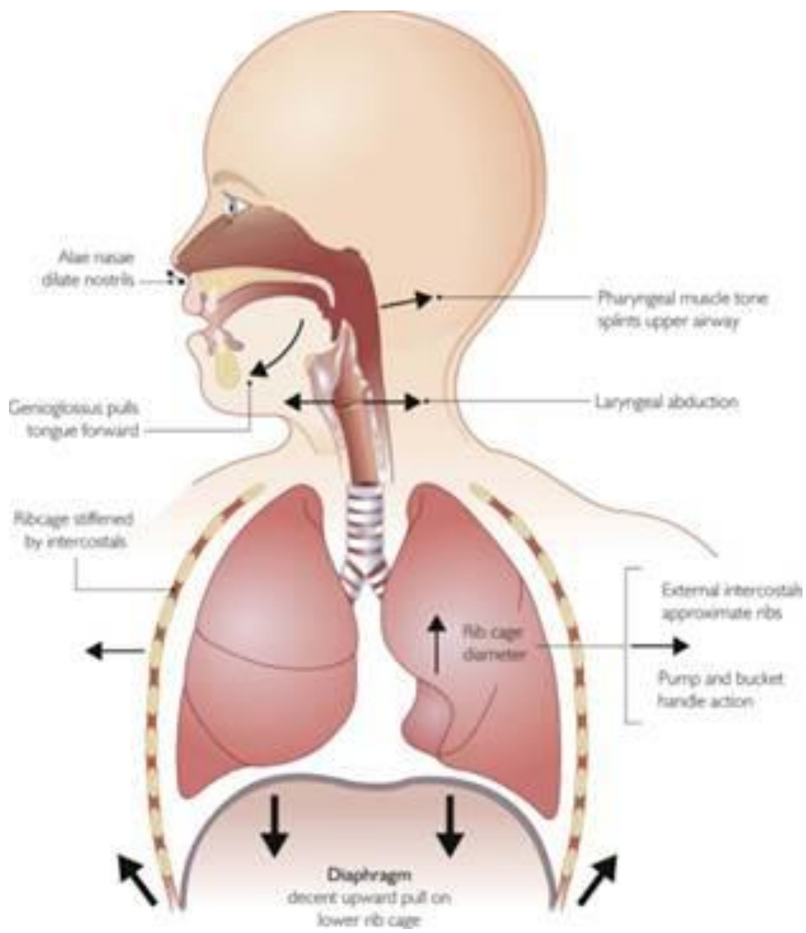
B. BreathableBaby commissioned Bureau Veritas, an independent testing lab, to evaluate their products as well as traditional crib bumpers for air permeability per ASTM D737 – *Standard Test Method for Air Permeability of Textile Fabrics* (found at http://www.astm.org/cgi-bin/resolver.cgi?D737). The same four BreathableBaby mesh liners were evaluated as in the pressure drop versus flow rate tests. In addition, 10 bumper products were evaluated (Products B-J), as well as using impermeable Saran Wrap and no sample at all to assess the limits of the test protocol. Each sample's air permeability was measured at a pressure of 125 Pa (equivalent to 1.27 cm H_2O) through a test head with a circular area of 38 square centimeters, a diameter of roughly 69.6 mm.

[‡] *cm H_2O = centimeter of water, a unit of pressure equivalent to the pressure exerted by a column of water 1 centimeter in height. This is the unit of pressure that is used, by convention, in studies of human physiology.

RESULTS

1. Discussion of normal infant breathing and possible mechanisms of bedding-related asphyxiation

Control of breathing and respiratory rhythm are influenced by the integration of multiple inputs from many areas within the brain, central and peripheral chemoreceptors, muscles, joints and peripheral pain receptors. Both central (brain stem) and peripheral (carotid) chemoreceptors are involved in modification of respiratory activity in response to changes in blood carbon dioxide, pH and oxygen. In addition there are several reflexes that are particularly active in infants that may impact on respiratory effort, but are not relevant to this discussion[5].



Pulmonary ventilation is obtained through changes in the ribcage dynamics that decrease pressure in the alveoli, leading to flow of air. At rest, the lungs and ribcage are in a situation of equilibrium determined by the sum of two contrasting forces: elastic inward recoil of the pulmonary parenchyma and outward elastic traction of the ribcage[6,7].

During normal breathing, air movement is accomplished primarily by contraction of the diaphragm, causing an increase in the vertical diameter of the ribcage, and to a lesser degree, especially in infants, by contraction of the intercostal muscles, causing changes in the antero-posterior diameter of the thorax by rotation of the ribs along their axis. Expansion of the ribcage during inspiration causes a reduction in intra-pleural pressure, and the lungs undergo passive expansion. At the end of quiet inspiration, intrapleural pressure reaches about -8 cm H_2O, which is the transpulmonary pressure distending the lungs. The expiratory phase, by contrast, is usually a passive phenomenon determined by the forces of elastic recoil of distended tissues: the greater the expansion of the lungs during inspiration, the greater its elastic recoil. During quiet expiration, the inspiratory muscles relax and the inward elastic recoil of the lungs results in deflation of the lungs. During deflation, the lungs and chest wall move as one unit. Airflow out of the lungs ceases when alveolar pressure equals atmospheric pressure (0 cm H_2O). The intervention of expiratory muscles, the most important ones being the muscles of the abdominal wall, occurs in physiological situations such as coughing, sneezing, crying or talking, or in some pathological conditions[6-8].

The forces that have to be overcome in order to move air through the respiratory system are not only the forces of elastic recoil of the lungs and chest but also the airway resistance. In the respiratory system some 30–40% of the resistance occurs at the nose. Infants are primarily nose breathers but they can establish oral breathing in the presence of nasal occlusion[6-9].

Flow of gases through a rigid tube is directly proportional to pressure at its entrance and inversely proportional to resistance[6]. The simple arithmetic relationship is made more complex by the compressibility of the human airway, which will narrow when pressure around it is greater than pressure within it. However, this latter aspect of ventilatory mechanics needs not be considered in the present context as it is relevant to the intrathoracic and not the extrathoracic (upper) airway which is the focus of concern in this discussion[§].

Restriction of flow through the airway leads to asphyxia and suffocation. Knowledge of normal pressures and flow of air through the respiratory tract, especially the upper airway, of infants, is essential to interpreting and placing into perspective the measurements of flow restriction produced by various products that will be reported later in this document.

Shardonofsky et al measured maximal inspiratory and expiratory airway pressures in 100 healthy infants (51 males, 49 females; age range, 0.06-3.76 years) by occluding the airway with a suitable face mask during a crying effort. The mean ± standard deviation (SD) maximal inspiratory pressure was 118±21 centimeters (cm) H_2O and the mean (±SD) expiratory pressure was 125±35 cm H_2O, respectively. Maximal inspiratory pressure was independent of age, sex,

[§] The intrathoracic airway includes the trachea and bronchial tubes, all contained within the chest. The extrathoracic airway includes the nose, throat and larynx, all of which are outside the chest and surrounded by atmospheric pressure.

and body measurements, while maximal expiratory pressure showed a low correlation with body weight[10].

Kassim et al studied respiratory muscle strength in 67 healthy term infants, a somewhat younger cohort. They found at birth a mean±SD maximal inspiratory pressure of 89±19 cm H_2O and mean expiratory pressure of 61.8±13.5 cm H_2O; these increased at 6 weeks of age to 101±15.2 cm H_2O and 82.6±19.4 cm H_2O, respectively[11].

Normal resting breathing parameters were measured in 7 day old infants by Schmalisch et al[12]. They documented a mean inspiratory time of 0.65±0.14 seconds, a mean expiratory time of 0.98±0.24 seconds, and tidal volume[**] of 5.57±1.06 milliliters/kilogram body weight. The average weight of their cohort was 3.28 kg, giving an average tidal volume of about 18 ml, so the average inspiratory flow of air was 28 ml/second (1.7 liters/minute) and average expiratory flow was 19 ml/second (1.1 liters/minute).

Djupesland and Lyholm used a specially designed nasal probe and determined that the total minimal cross-sectional area of the nose in newborns is 21 square millimeters ($mm^{2)}$ increasing to 35 mm^2 at 1 year of age[13]. The diameter of the nasal airway (assuming circularity) is 5.2–6.7 mm, which equates to 109-141% of the diameter of the test apparatus used by Dr. Raynor, but only 7.5-9.6% of the test apparatus diameter used in the air permeability tests conducted by Bureau Veritas. The cross-sectional area of the trachea is considerably smaller, estimated by Griscom et al[14,15], using radiologic techniques, to be 16mm^2 at 3 weeks of age and 17 mm^2 at 5 months of age.

The role of bedding in infant asphyxiation leading to SIDS.

Studies have implicated the infant sleeping environment as a risk factor for SIDS, particularly a soft sleep surface and pillows[16-18]. In support of theories regarding the role of environmental triggers, there is compelling epidemiologic evidence that prone positioning confers significant risk and that public health programs recommending “back to sleep” have been responsible for a drop in the incidence of SIDS[3]. This and the finding of infants found dead with their airways covered by bedding lends support to theories related to accidental suffocation as an etiology in at least some children[19,20]. A triple-risk model has been proposed suggesting that SIDS occurs in infants with underlying vulnerability (eg, genetic pattern, brainstem abnormality) who

[**]Tidal volume is the volume of air that is inhaled or exhaled in a single relaxed breath. Tidal breathing (alluded to below) is normal resting breathing.

experience a trigger event (eg, airflow obstruction, maternal smoking or infection), at a vulnerable developmental stage of the central nervous or immune system[21]. However, mechanisms continue to be speculative. Serotonin-mediated responses to decreases in blood oxygen and increases in carbon dioxide have been implicated, as well as other abnormalities of the autonomic nervous system[22]. Furthermore, it has been suggested that accidental suffocation is a gradual process associated with rebreathing of exhaled air and carbon dioxide accumulation rather than abrupt and complete obstruction of breathing[23,24].

2. Results of epidemiologic analysis of CPSC databases on morbidity and mortality associated with BreathableBaby Mesh Liners

Econometrica's analysis of incidents in the four CPSC databases indicates that there are a negligible number of reported incidents (three over the 7-year period from 2009 through 2015) in which a mesh crib liner was present. Specifically, their study found that, with respect to mesh crib liners, there were no fatalities, no injuries treated in emergency departments, no injuries that required medical attention, and no incidents that involved a risk of suffocation.

One of the three reported incidents involved a child of 4 months with her head pressed against the liner; she had red marks on her face but was not injured. Econometrica interpreted this to represent a case where use of a mesh crib liner provided a substantial safety benefit. The other two reports involved arm/leg entrapments that occurred in cribs with mesh liners installed but did not involve injuries requiring medical attention. Econometrica's report describes these as cases in which the liner simply failed to prevent an entrapment injury rather than being a product that contributed to the injury.

The report further states that "*The NEISS data also suggest that mesh crib liners provide a safety benefit by reducing the rate of limb entrapments in crib slats and rails. Limb entrapments associated with cribs account for an estimated 280 ED-treated injuries annually, accounting for 5% of all estimated ED-treated injuries associated with cribs. Our analysis of 2009-2015 IPII database records shows that more than half of all injury incidents that consumers reported to CPSC…associate with cribs involved arm or leg entrapments. Based on our analysis of the CPSC incidents reports since 2009, mesh crib liners appear to provide a potentially substantial safety benefit in the form of reduced number of limb entrapment injuries without posing a potential suffocation risk*."

It should be noted that the Econometrica study sought out all incidents associated with mesh crib liners and the frequency and type of injuries associated with limb entrapment in cribs. So while all incidents of limb entrapment are cataloged, whether they involved mesh liners or not, those involving any suffocation-related incidents were not enumerated as none were found to have occurred in association with mesh liners.

3. Laboratory testing data on air permeability of the BreathableBaby Mesh Liners

A. Findings from Dr. Raynor's laboratory:

The relationships of pressure drop versus flow rate for the four test fabrics are shown in Figure 2. Table 1 shows pressure drop predictions for the test fabrics at air flow rates of 4 and 8 L/min.

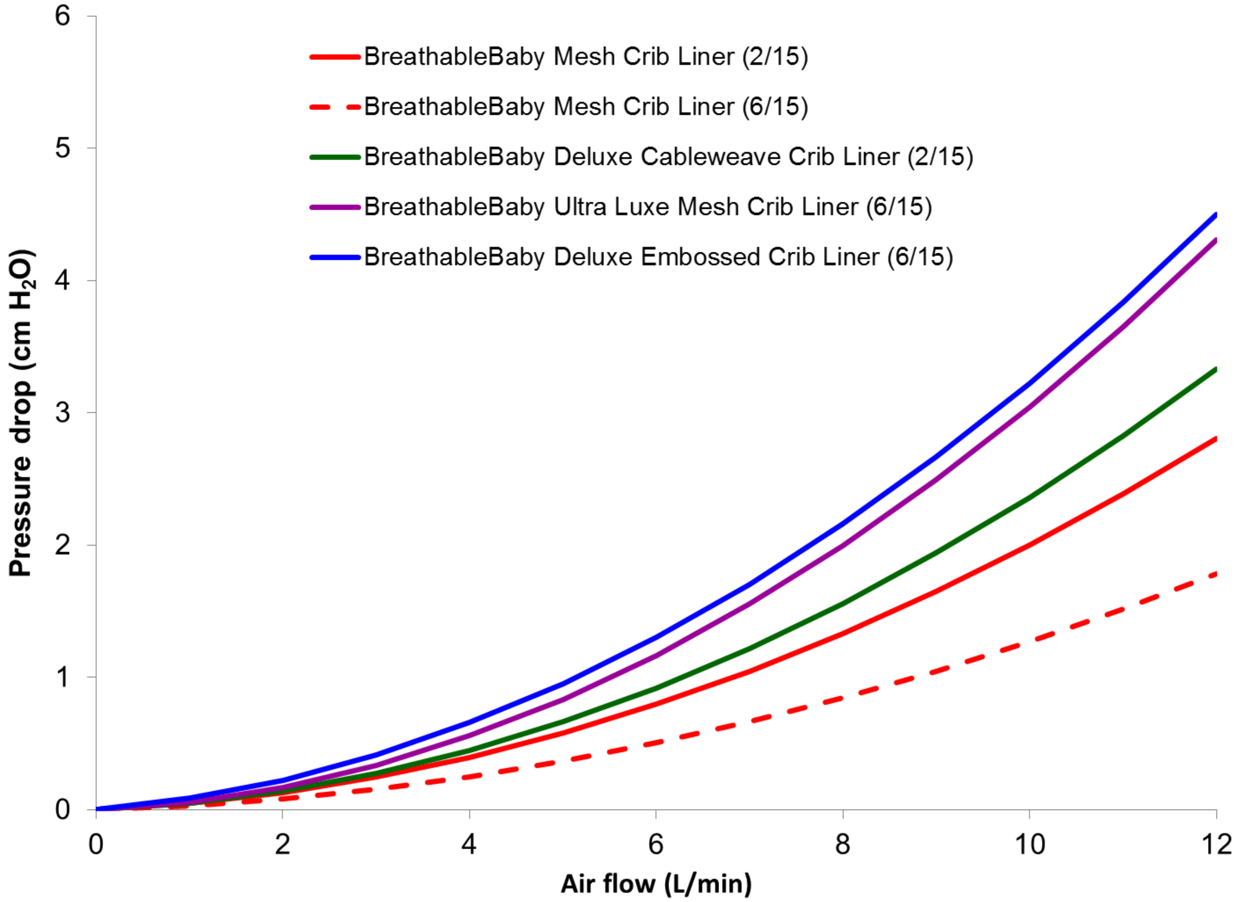


FIGURE 2. Polynomial regression lines of pressure drop versus air flow rate for the test fabrics, corrected for the relationship between pressure drop and flow when no liner or bumper is present.

TABLE 1: Pressure drops predicted at flow rates of 4 and 8 L/min from equations fit to date taken during tests with BreathableBaby crib liners.

Crib liner	Pressure drop estimate (cm H_2O) at flow rate = 4 L/min	Pressure drop estimate (cm H_2O) at flow rate = 8 L/min
BreathableBaby Mesh Crib Liner (February 2015)	0.40	1.33
BreathableBaby Mesh Crib Liner (June 2015)	0.25	0.85
BreathableBaby Deluxe Cableweave Crib Liner (February 2015)	0.45	1.56
BreathableBaby Ultra Luxe Mesh Crib Liner (June 2015)	0.56	2.00
BreathableBaby Deluxe Embossed Crib Liner (June 2015)	0.66	2.16

B. Permeability testing by Bureau Veritas

The measurements performed by Bureau Veritas are presented in Table 2. They show that mesh crib liners have a high degree of air permeability. BreathableBaby's 4 crib liner products tested between a range of 385 to 1013 cubic feet per minute of airflow. On average, BreathableBaby's 4 crib liner products were over 10 times as permeable to air as the traditional crib bumpers that were also tested. BreathableBaby's most permeable crib liner was over 46 times more permeable to air than the least permeable traditional crib bumper tested.

TABLE 2. Air permeability measured by Bureau Veritas for BreathableBaby crib liners and competitor products, as well as for impermeable Saran Wrap and with no sample present.

Product Description	Air Permeability (cubic feet / minute)
No sample present	1460
BreathableBaby Mesh Crib Liner	1013

BreathableBaby Deluxe Cableweave Crib Liner	537
BreathableBaby Ultra Luxe Mesh Crib Liner	385
BreathableBaby Deluxe Embossed Crib Liner	521
Product B	70.2
Product C1	48.3
Product C2	41.6
Product D	46.4
Product E	45.4
Product F	39.8
Product G	28.4
Product H	28.1
Product I	22.8
Product J	21.7
Saran Wrap	0

DISCUSSION

In judging the safety of BreathableBaby Mesh products, we have the opportunity to synthesize two complementary types of research. On the one hand, we have the epidemiologic data that has been published by Scheers et al and further compiled by the Econometrica research company and on the other hand the physical testing performed by Dr. Raynor and by Bureau Veritas.

The study by Scheers et al. is compelling to us as it provided significant detail on suffocation deaths and near-deaths attributable to the use of conventional crib bumpers as well as other injuries. Those authors seem not to have found any events associated with the use of mesh liner products, as none were mentioned in their report and they supported the use of mesh liners as a replacement for crib bumpers by stating in their discussion that *"Mesh bumpers (sic) are breathable and thin and may reduce the likelihood of slat entrapment and climb outs…These…designs were excluded from the State of Maryland's ban on the sale of crib bumpers"*. While it is not clear what proportion of the denominator infant population used BreathableBaby Mesh products during the period of their analysis (which went as far back as 1985 but specifically identified an apparent increase in death rate attributable to crib bumpers between 2006-2012), the company reports sales of over 2.5 million units since 2002, so a significant reduction in risk, at the very least, can be inferred. The study performed by Econometrica, commissioned by BreathableBaby, specifically searched for incidents associated with the use of mesh liners in the CPSC data bases and found nothing except 3 reports of minor injuries reported by consumers that were not attributable to the liners.

Overall, while there is a possibility that suffocation or limb entrapment events were missed by the CPSC database, and it is difficult to compare estimates of incidence without a clearer understanding of the relative prevalence of conventional crib bumper use vs mesh liner use, this line of data makes a compelling argument for relative safety of mesh liners compared with conventional crib bumpers.

The physical testing done by Dr. Raynor and by Bureau Veritas use different techniques, and each presents some challenges in extrapolation to real-life settings with infants. In particular, the diameter of the air flow region in the Bureau Veritas tests is more than 10X larger in diameter than an infant's nostril. Nonetheless, the Bureau Veritas data in Table 2 demonstrate that the BreathableBaby crib liners are all much more permeable to air than the traditional crib bumpers evaluated. Setting aside the most permeable product, Product B, the least permeable BreathableBaby crib liner allows 8X or greater air flow relative to each of the remaining traditional crib bumpers in these tests. These differences suggest a significant advantage for the mesh crib liners versus the traditional bumper products.

The test apparatus developed by Dr. Raynor, while not a dynamic system that simulates tidal breathing, utilized a tube diameter very similar to an infant's nostril diameter and measured pressure drops through crib liners at air flow rates relevant to infant breathing rates. Dr. Raynor's data show that only a trivial increase in pressure (<1 cm H_2O) is observed at air flows of 1-2 liters/minute through the liners, which is the physiologic range of interest. As noted, normal tidal respiration is associated with inspiratory pressures of <10 cm H_2O, and the publications cited show that infants can generate maximum inspiratory and expiratory pressures up to 100 cm H_2O. Thus, the pressure drop through BreathableBaby mesh liners is more than two orders of magnitude lower than the maximum inspiratory and expiratory pressures that infants can generate. The relatively minimal pressure drop associated with the BreathableBaby liners suggests that they are likely to have minimal impact on the inspiration and exhalation rates of infants were they to breathe directly through the crib liners.

The Bureau Veritas tests and the measurements made by Dr. Raynor use experimental methods that do not directly replicate the breathing process of infants. In addition, the two approaches are not directly comparable due to differences in tube diameters and pressure ranges. Therefore, we must be cautious in trying to extrapolate results to real-life situations. Nonetheless, both sets of data suggest reassuringly high permeability to the flow of gases through BreathableBaby crib liners, and greater permeability than what is found in currently marketed crib bumper products.

As noted, the combination of laboratory and epidemiologic data make a compelling argument for the safety of the BreathableBaby products, despite the limitations of both approaches independently.

CONCLUSIONS

In summary, we believe that there is reasonable evidence from the epidemiologic data and from the laboratory testing data to support the conclusion that BreathableBaby mesh crib liners are safe because they do not present a significant restriction to infant breathing airflows. There is no reason to believe that they would increase the risk of suffocation hazards for infants. Ongoing surveillance through the established CPSC databases would, of course, be appropriate to confirm this conclusion.

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